

Application No. 09/715,036

Attorney Docket 077281/0104

REMARKS**General Comments**

Examiners Gibbs and Lacourciere are thanked for helpful discussions during the February 24, 2004 Interview. During the interview, Applicants discussed the rejection of claims 27-28 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Because "peanut allergen gene" is co-extensive with "*Ara h* gene," Applicants agreed to amend claims 27-28, thereby avoiding the rejection of record.

The 103 art of record was also discussed during the interview. Specifically, Applicants explained that there is no motivation to combine Tada et al. with Kleber-Janke et al. Moreover, even if there were a motivation to combine, the combination of Tada et al. with Kleber-Janke et al. would not render the present obvious. Applicants also explained how Kleber-Janke et al. teaches away from the present invention by teaching immunotherapeutic reagents. In view of these discussions, Examiner Gibbs agreed to revisit the 103 art of record.

Status of the Claims

Claims 1-28 are pending, with elected claims 21-28 under examination. Claim 27 has been amended. No new matter has been added.

Rejections- 35 U.S.C. § 112, first paragraph

Claims 27-28 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Specifically, the claims are rejected because the specification allegedly does not define "peanut allergen gene." See Office Action, page 3.

As discussed during the Examiner interview, "peanut allergen gene" is co-extensive with "*Ara h* gene." Conventionally, peanut allergen genes are denoted by referring to the Latin name for peanut (*Arachis hypogaea*), followed by a number. Accordingly, any peanut allergen gene would inherently reference *Ara h*, and thus, the terms are co-extensive. In an effort to advance prosecution, however, present claim 27 recites *Ara h* gene. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

Application No. 09/715,036

Attorney Docket 077281/0104

Rejections- 35 U.S.C. § 103**Tada et al. and Kleber-Janke et al. do not render the present invention unpatentable.**

Claim 21, 22, 23, and 25-28 are rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Tada et al., in view of Kleber-Janke et al. See Office Action, page 6. The claims are rejected on the grounds that the combination of references allegedly renders the present invention obvious. The Office takes the position that since Tada et al allegedly teaches antisense suppression of a 16 KDa rice allergen, one of skill in the art would have been motivated to identify a homologous region from more than one *Ara h* allergen gene and then clone the identified *Ara h* homologous region in the antisense orientation for peanut transformation using the combined teachings of Kleber-Janke et al. and Tada et al. See Office Action, pages 7-10. Applicants respectfully traverse this rejection on the grounds that the reasons made of record fail to establish a reason for combining the cited art and the combination of references do not render the present invention obvious.

There is no motivation to combine references

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine reference teachings. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP § 2143.01 (emphasis in original). When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001).

In other words, an obviousness holding must present "a showing of a suggestion, teaching, or motivation to combine the prior art references." See, e.g., *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ 2d 1456, 1459 (Fed. Cir. 2000). This precedent has been reinforced in numerous decisions, and cannot be dispensed with. "Our case law makes clear that the best defense against the subtle but

Application No. 09/715,036

Attorney Docket 077281/0104

powerful attraction of an obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."; *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ 2d 1635, 1637 (Fed. Cir. 1998).

In *In re Fine*, the claims were directed to a system for detecting and measuring minute quantities on *nitrogen* compounds comprising a gas chromatograph, a converter which converts nitrogen compounds into nitric oxide by combustion, and a nitric oxide detector. The primary reference disclosed a system for monitoring *sulfur* compounds comprising a chromatograph, combustion means, and a detector, and the secondary reference taught nitric oxide detectors. The examiner and the Board asserted that it would have been within the skill of the art to substitute one type of detector for another in the system of the primary reference, however, the court found that there was no support or explanation of this conclusion and reversed. *In re Fine* 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) ("teachings of references can be combined only if there is some suggestion or incentive to do so.").

Applying these standards to the present rejection, the Office has failed to provide a reason why one skilled in the art, absent knowledge of the present invention, would be motivated to identify a homologous region from more than one *Ara h* allergen gene and then clone an identified *Ara h* homologous region in the antisense orientation into a vector for peanut transformation. As neither Tada et al. nor Kleber-Janke et al., alone or together, disclose a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed, the cited art could not render the present invention unpatentable.

Specifically, neither Tada et al. nor Kleber-Janke et al., alone or together, teach or even suggest identifying a region homologous to more than one *Ara h* gene and then cloning the homologous *Ara h* region in the antisense orientation for peanut transformation. In contrast, Tada et al. discloses "14-16 kDa allergens are multigene products" and "[m]ore than 10 homologous cDNA clones encoding the 14-16 kDa allergens have been identified" (See Tada et al., page 341, first column). Yet, despite this explicit disclosure, Tada et al. neither teaches nor suggests identifying a region homologous to more than one allergen for cloning in

Application No. 09/715,036

Attorney Docket 077281/0104

the antisense orientation. In fact, Tada et al. teaches a single clone denoted as RA17(See Tada et al., page 341, second column) for cloning in the antisense orientation. Furthermore, Kleber-Janke et al. neither teaches nor suggests identifying a region homologous to more than one *Ara h* gene and transforming a peanut with an antisense *Ara h* construct. Even if a motivation for combining the references had been established, the combination of references would not render the present invention obvious. Accordingly, the rejection is improper and should be withdrawn.

Kleber-Janke et al. teaches away from the present invention

As discussed during the Examiner interview, nowhere does Kleber-Janke et al. discuss transforming a peanut plant with an antisense *Ara h* gene, let alone a region homologous to more than one *Ara h* gene. As one would expect from an article published in *International Archives of Allergy and Immunology*, Kleber-Janke et al. only discloses the sequence of *Ara h* genes in the context of IgE-binding properties and patient reactivity profiles, not in the context of transgenic plants having reduced allergen content.

In fact, Kleber-Janke et al. teaches away from the methods of the present invention. In contrast with the present invention, Kleber-Janke et al. teaches developing "immunotherapeutic reagents" and "sensitive test systems for detecting allergens in industrial food products". See Kleber-Janke et al., page 272, second column, final paragraph. Clearly, immunotherapeutic reagents and sensitive test systems would not render a method for producing a transgenic peanut plant obvious. Therefore, even if a motivation to combine references had been established, the combination of references would not render the instant invention obvious. Again, for this reason alone, the rejection should be withdrawn.

An obviousness rejection can not be based upon unqualified hindsight reasoning.

To prevent the use of hindsight based on the invention to defeat patentability of an invention, the Federal Circuit requires the PTO to show a motivation to combine the references that create the case of obviousness. In other words, the PTO must show reasons that the skilled artisan, confronted with the same problems as the inventor and lacking knowledge of the claimed invention, would choose the elements from the cited references for

Application No. 09/715,036

Attorney Docket 077281/0104

combination in the manner claimed. *In re Rouffet*, 47 USPQ2d 1453, 1457-8 (Fed. Cir. 1998). Importantly, with respect to this motivation, the Federal Circuit placed the burden on the PTO to present "clear and particular" evidence showing motivation to combine. *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999).

Since no motivation has been established for combining the teachings of the references, Applicants' specification has been used as a hindsight road map to recreate the claimed invention. To prevent the use of hindsight, "[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done." See MPEP § 2142. That has not been done in this case.

In summary, none of the cited references, alone or together, disclose a method for identifying a region homologous to more than one *Ara h* gene and transforming a peanut plant with an antisense *Ara h* homologous region. As a result, there is no *prima facie* case of obviousness established with respect to claims 21-28.

Klein et al. does not remedy the deficiencies of Tada et al. and Kleber-Janke et al.

Claims 21-22 and 24-26 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Tada et al. and Kleber-Janke et al., in further view of Klein et al. See Office Action, page 10. Applicants respectfully traverse this rejection.

For reasons already advanced, neither Tada et al. nor Kleber-Janke et al., alone or together, disclose a method for identifying a region homologous to more than one *Ara h* gene and transforming a peanut plant with an antisense *Ara h* homologous region. Since Klein et al. does not remedy the deficiencies of Tada et al. and Kleber-Janke et al., the combination of references does not render the present invention obvious. As there is no *prima facie* obviousness with respect to claims 21-22 and 24-26, the rejection is improper and should be withdrawn.

Application No. 09/715,036

Attorney Docket 077281/0104

CONCLUSION

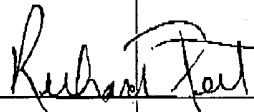
As the above-presented amendment and remarks address and avoid each rejection presented by the Examiner, withdrawal of the rejections and allowance of each claim is respectfully requested. No new matter has been added.

If there are any questions concerning this application, the Examiner is courteously invited to contact the undersigned counsel.

Respectfully submitted,

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By



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